

COMPETENT AUTHORITY CERTIFICATION

1200 New Jersey Avenue Southeast
Washington, D.C. 20590

FOR A TYPE B(U)

East Building, PHH-23

RADIOACTIVE MATERIALS PACKAGE DESIGN CERTIFICATE USA/0697/B(U)-96, REVISION 6

REVALIDATION OF CANADIAN COMPETENT AUTHORITY CERTIFICATE CDN/2078/B(U)-96

This certifies that the radioactive material package design described is hereby approved for use within the United States for import and export shipments only. Shipments must be made in accordance with the applicable regulations of the International Atomic Energy Agency¹ and the United States of America².

- 1. Package Identification MDS Nordion F-458/F-245, F-458/F-247, F-458/F-251, F-458/F-251 MK2, F-458/F-318 and F-458/F-448 Transport Packages.
- 2. <u>Package Description and Authorized Radioactive Contents</u> as described in Canada Certificate of Competent Authority CDN/2078/B(U)-96, Revision 7 (attached).

3. <u>General Conditions</u> -

- a. Each user of this certificate must have in his possession a copy of this certificate and all documents necessary to properly prepare the package for transportation. The user shall prepare the package for shipment in accordance with the documentation and applicable regulations.
- b. Each user of this certificate, other than the original petitioner, shall register his identity in writing to the Office of Hazardous Materials Technology, (PHH-23), Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington D.C. 20590-0001.
- c. This certificate does not relieve any consignor or carrier from compliance with any requirement of the Government of any country through or into which the package is to be transported.

¹ "Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised), No. TS-R-1 (ST-1, Revised)," published by the International Atomic Energy Agency(IAEA), Vienna, Austria.

² Title 49, Code of Federal Regulations, Parts 100-199, United States of America.

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d. Records of Quality Assurance activities required by Paragraph 310 of the IAEA regulations shall be maintained and made available to the authorized officials for at least three years after the last shipment authorized by this certificate. Consignors in the United States exporting shipments under this certificate shall satisfy the applicable requirements of Subpart H of 10 CFR 71.

4. Special Conditions -

- a. For shipments of radioactive material not in special form:
 - (i) The radioactive material must be packaged in a leakproof insert.
 - (ii) The maximum decay heat is 6.1 watts per package.
 - (iii) The leakproof inset O-ring must be tested to demonstrate a leakage rate not more than 1E-7 ref-cm3/s prior to use. This test may be performed prior to loading the contents in the leakproof insert.
 - (iv) Radioactive iodine is limited to a quantity of 30 A2 per package.
 - (v) After loading and prior to shipment of Sr-90 or Mo-99, the seals of the leakproof insert must show no leakage when tested to a sensitivity of at least 1E-3 ref-cm3/s.
- b. The shipper must provide the consignee special instructions for safely opening the package. The instructions must give special consideration to any byproducts generated by the radiolysis of water.
- 5. Marking and Labeling The package shall bear the marking USA/0697/B(U)-96 in addition to other required markings and labeling.
- 6. Expiration Date This certificate expires on October 31, 2020.

CERTIFICATE USA/0697/B(U)-96, REVISION 6

This certificate is issued in accordance with paragraph 808 of the IAEA Regulations and Section 173.473 of Title 49 of the Code of Federal Regulations, in response to the September 18, 2015 petition by Nordion (Canada) Inc., Ottawa, Ontario, and in consideration of other information on file in this Office.

Certified By:

Dr. Magdy El-Sibaie

Associate Administrator for Hazardous Materials Safety

Oct 23 2015

(DATE)

Revision 6 - Issued to revalidate Canadian Certificate of Competent Authority CDN/2078/B(U)-96, Rev. 7, with the indicated conditions.



Canadian Certificate No.: CDN/2078/B(U)-96 (Rev. 7)

Issue Date: **Sep-14-2015**Expiry Date: **Oct-31-2020**CNSC File: **20.42.242**

CNSC File: 30-A2-243-0

Certificate

CDN/2078/B(U)-96 (Rev. 7)

Transport Package Design

The transport package design identified below is certified by the Canadian Nuclear Safety Commission pursuant to paragraph 21(1)(h) of the *Nuclear Safety and Control Act* and Subsection 10(1) of the *Packaging and Transport of Nuclear Substances Regulations*, 2015 and to the IAEA's *Regulations for the Safe Transport of Radioactive Material*, 2012 Edition.

REGISTRATION OF USE OF PACKAGES

All users of this authorization shall register their identity in writing with the Canadian Nuclear Safety Commission prior to the first use of this authorization and shall certify that they possess the instructions necessary for preparation of the package for shipment.

PACKAGE IDENTIFICATION

Designer: Nordion (Canada) Inc.

Make/Model: F-458/F-245; F-247; F-251; F-251 MKII; F-318 and F-448

Mode of Transport: Air, Sea, Road, Rail

IDENTIFICATION MARK

The package shall bear the competent authority identification mark "CDN/2078/B(U)-96".

PACKAGE DESCRIPTION

The packaging consists of a containment system, a shielding vessel and an outer container. The containment system consists of a sealed source capsule which meets the requirements for special form radiactive material, a C-133 welded sealed capsule within an F-336 tungsten alloy insert or an F-248, F-242, F-256 or F-320 leak proof insert. The leak proof insert consists of a stainless steel body and a lid that is screwed into place and sealed with an O-ring.

The shielding consists of an F-251, F-251 MKII, F-318, F-245 or F-247 vessel made of depleted uranium encased in stainless steel or an F-448 vessel made of lead encased in stainless steel.

The outer container consists of a double-wall cylindrical stainless steel drum closed by a lid and six M10 stainless steel bolts. The void between the two walls is filled with polyurethane foam for thermal and impact protection. Two vent holes, closed by a plastic pipe thread plug are located on the body of the drum and two are located on the lid.







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The various packaging models are further shown on Nordion Drawings Nos. F-458/F-245: F624501-002 (Issue E); F-458/F-247: F624701-002 (Issue E); F-458/F-251 and F-251 MKII: F625101-002 (Issue F); F-458/F-318: F631801-002 (Issue E) and F-458/F-448: F644801-002 (Issue E).

An illustration of the package is shown in the attached Nordion Drawing No. F-458 (Issue A).

Any modification to the package design must be submitted to the CNSC for approval prior to implementation.

The total mass of each package combination is as follows:

F-458/F-251 and F-458/F-251 MKII: 167 kg

F-458-F-318: 164 kg F-458/F-245: 153 kg

F-458/F-247: 125 kg

F-458/F-448: 138 kg

The configuration of the F-458 packaging is as follows:

Shape: Cylinder Shielding: Lead or Depleted Uranium

Mass: n/a Outer Casing: Stainless Steel

Length:n/aHeight:494 mmWidth:n/aDiameter:400 mm

AUTHORIZED RADIOACTIVE CONTENTS

The radioactive contents for the various configurations of the F-458 Transport Package are listed in Appendix A attached.

QUALITY ASSURANCE

Quality assurance for the design, manufacture, testing, documentation, use, maintenance and inspection of the package shall be in accordance with:

- Nordion Document No. IN/QA 0224 Z000 (8)* "Radioactive Material Transport Package Quality Plan"
- Nordion Document No. IN/QA 0562 A000 (4)* "Sealed Source Quality Plan"
- Nordion Document No. IS/DS 1789 F458 (12) "Design, Manufacturing and Operating Specification for the F-458 Family of Transport Packages"
- Packaging and Transport of Nuclear Substances Regulations, 2015







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- IAEA Regulations for the Safe Transport of Radioactive Material, 2012 Edition
- * or latest current revision

SHIPMENT

The preparation for shipment of the package shall be in accordance with:

- Nordion Document No. IS/DS 1789 F458 (12) "Design, Manufacturing and Operating Specification for the F-458 Family of Transport Packages"
- Packaging and Transport of Nuclear Substances Regulations, 2015
- IAEA Regulations for the Safe Transport of Radioactive Material, 2012 Edition

This certificate does not relieve the consignor from compliance with any requirement of the government of any country through or into which the package will be transported.

S. Faille

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Designated Officer pursuant to paragraph 37(2)(a) of the Nuclear Safety and Control Act





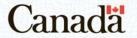


Appendix A

The radioactive contents for the various configurations of the F-458 Transport Packages are listed in the following tables:

Package Configurations and Authorized Radioactive Contents for F-458/F-251 and F-458/F-318

Isotope	F-251 or F-318 with F-248 insert	F-251 or F-318 with F-320 insert	F-251 or F-318 with F-368 insert	Chemical and Physical Form		
I-131	20 TBq (540 Ci)	20 TBq (540 Ci)	20 TBq (540 Ci)	Solid		
I-131	7.4 TBq (200 Ci)	13 TBq (351 Ci)		Aqueous NaOH solution or aqueous NaOH with up to 0.02 M Na ₂ SO ₄		
Ir-192	-		300 TBq (8100 Ci)	Special Form capsule		
Mo-99/ Tc-99m	37 TBq (1000 Ci)	55.5 TBq (1500 Ci)		Solid or aqueous NaOH solution or aqueous NaOH with up to 1 M NH ₄ NO ₃ or up to 0.4% NaOCl		
Mo-99/ Tc-99m		21.5 TBq (581 Ci)		Aqueous NH ₄ OH solution		
Sr-90/ Y-90	18.5 TBq (500 Ci)	18.5 TBq (500 Ci)		Solid		
Sr-90/ Y-90	6.4 TBq (173 Ci)	11.1 TBq (300 Ci)		Liquid in up to 1 N HCl		
Y-90	18.5 TBq (500 Ci)	18.5 TBq (500 Ci)		Solid		
Y-90	6.4 TBq (173 Ci)	11.1 TBq (300 Ci)		Liquid in 0.04 N HCl		





Package Configurations and Authorized Radioactive Contents for F-458/F-245 and F-458/F-247

	Package Configuration					
Isotope	F-245 with F-248 insert	F-247 with F-242 insert	F-245 with F-336 insert	Chemical and Physical Form		
Co-60			275 GBq (7.4 Ci)	Solid		
I-131	7500 GBq (202 Ci)	3300 GBq (89 Ci)	-	Solid or aqueous NaOH solution or aqueous NaOH with up to 0.2 M Na ₂ S0 ₄		
Ir-192		37 TBq (1000 Ci)		Solid pellets		
Ir-192			300 TBq (8100 Ci)	Solid pellets in a C-133 capsule		
Ir-192		110 TBq (2970 Ci)	300 TBq (8100 Ci)	Special form capsule		
Mo-99/ Tc-99m	37 TBq (1000 Ci)	25 TBq (676 Ci)		Solid or aqueous NaOH solution or aqueous NaOH solution with up to 1 M NH ₄ NO ₃ or up to 0.4% NaOCl		

Package Configurations and Authorized Radioactive Contents for F-458/F-448 in F-256 Leakproof Insert

	Package Configuration					
Isotope	F-448/F-256	F-448/F-256/F-389	Chemical and Physical Form			
I-125	7,400 GBq (200 Ci)	7,400 GBq (200 Ci)	Solid or Aqueous NaOH solution			
I-131	5,180 GBq (140 Ci)	10,000 GBq (270 Ci)	Solid or Aqueous NaOH solution or Aqueous NaOH solution with 0.02 M Na ₂ SO ₄			
Mo-99/ Tc-99m	555 GBq (15 Ci)	1,110 GBq (30 Ci)	Solid or Aqueous NaOH solution or Aqueous NaOH with 1 M NH ₄ NO ₃ or up to 0.4% NaOCl			
Y-90	16,000 GBq (432 Ci)		Solid or Liquid in 0.04 N HC1			
Sr-90/Y-90	16,000 GBq (432 Ci)		Solid or Liquid in 1 N HC1			







Package Configurations and Authorized Radioactive Contents for F-458/F-448 in Special Form Sealed Sources

	Package Configuration					
Isotope	F-448	F-448/F-174	F-448/F-286	F-448/F-382		
Co-60	4.0 GBq	15.0 GBq	4.0 GBq	15.0 GBq		
	(0.1 Ci)	(0.4 Ci)	(0.1 Ci)	(0.4 Ci)		
Ir-192	2,405 GBq	9,250 GBq	4,800 GBq	33,300 GBq		
	(65 Ci)	(250 Ci)	(130 Ci)	(900 Ci)		
Sb-124	7.4 GBq	11.1 GBq	7.4 GBq	44.4 GBq		
	(0.2 Ci)	(0.3 Ci)	(0.2 Ci)	(1.2 Ci)		
Y-90	18,000 GBq	18,000 GBq	18,000 GBq	18,000 GBq		
	(486 Ci)	(486 Ci)	(486 Ci)	(486 Ci)		
Sr-90/Y-90	18,000 GBq	18,000 GBq	18,000 GBq	18,000 GBq		
	(486 Ci)	(486 Ci)	(486 Ci)	(486 Ci)		









NOTES

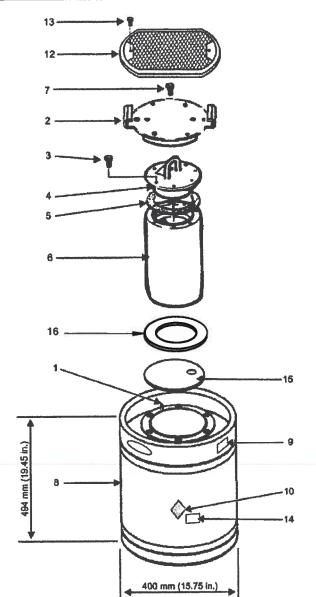
Revision 5: January 23, 2013. Addition of Mo-99/Tc-99m in the form of NH₄OH solution to the authorized radioactive contents.

Revision 6: April 25, 2013. Certificate revised to reflect addition of an optional seating gasket.

Revision 7: September 14, 2015. Certificate renewed.





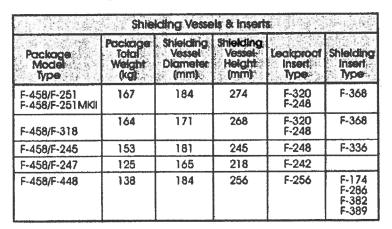


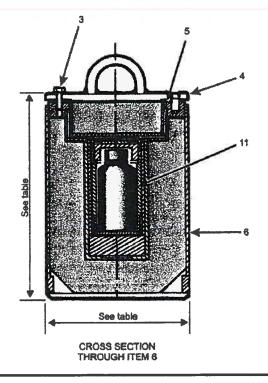
Parts List

- 1. Wire seal on guide pin
- 2. Lid
- 3/8 16UNC hex head cap screws, SAE J429, Gr. 5, (F-245, F-247 and F-251 – 4 pcs., F-448, F-251 MKII and F-318 – 6 pcs.)
- 4. Shielded plug
- 5. Neoprene gasket
- 6. Shielding vessel
- 7. Stainless steel bolt M10 x 30 mm long (6)
- 8. Stainless steel cylinder
- 9. Shipping container identification and radiation caution label (2)
- 10. Radioactive Category Labels (2): on two opposite sides
- 11. Leakproof insert and radioactive contents
- 12. Heat screen, See Note 5.
- 13. Stainless steel bolt M8 x 16 mm long (2)
- UN Number Labels (2): one next to each of the radioactive category label
- 15. Bottom spacer disk (as required for F-245, F-247, F-448)
- 16. Optional Gasket

Notes

- 1. Meets IAEA Type B(U) requirements
- 2. CNSC Certificate CDN/2078/B(U)-96
- 3. Prepare for shipment in accordance with IS/PP 1693 F458
- 4. Supplemental shielding inserts may be used in some configurations
- Supplemental heat screen to be used for shipments of Ir-192 in excess of 150 TBq







447 March Road Ottawa, ON Canada, K2K 1X8 Tel: 613-592-3400 Fax: 613-482-4650

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TITLE

F-458 Transport Packaging

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U.S. Department of Transportation

East Building, PHH-23 1200 New Jersey Avenue SE Washington, D.C. 20590

Pipeline and Hazardous Materials Safety Administration

CERTIFICATE NUMBER: USA/0697/B(U)-96, Revision 6

ORIGINAL REGISTRANT(S):

Luc Desgagne Senior Licensing Coordinator Nordion (Canada) Inc. 447 March Road Ottawa, K2K 1X8 Canada

Jackie Kavanagh Manager, Facility & Transportation Licensing Nordion (Canada) Inc. 447 March Road Ottawa, K2K 1X8 Canada

REGISTERED USER(S):

Mr. R.D. Donny Dicharry President Source Production and Equipment Company, Inc. 113 Teal Street St. Rose, 70087-9691 USA

Henk Doornebos Manager Distribution Mallinckrodt Medical BV Westerduinweg 3 PO Box 3 1755 ZG Petten, The Netherlands Kelly Richardt Regulatory and Quality Manager Source Production and Equipment Company, Inc. 113 Teal St. St. Rose, 70087 USA

Carter Roberts
Type B Quality Assurance Supervisor
University of Missouri-Columbia
Research Reactor Center
University of Missouri-Columbia
Research Park
Columbia, 65211
USA

Amber Gaddy Compliance Specialist University of Missouri-Columbia 1513 Research Park Columbia, 65211 USA

Mr. Juul Rijpkema Manager Regulatory Compliance and Transport Security Mallinckrodt Medical BV Westerduinweg 3 P.O. Box 3 1755 ZG Petten , The Netherlands 1755 The Netherlands

Mr. Mike Rose QAM and ARSO Industrial Nuclear Company, Inc. 14320 Wicks Blvd. San Leandro, CA 94577 Mr. Henk Doornebos Manager Distribution Covidien Petten Westernduinweg 3 1755LE Petten P.O. Box 3 Petten, Netherlands 1755ZG Netherlands

John Ernst Assoc. Director, Regulatory Assurance University of Missouri-Columbia Research Reactor 1513 Research Park Columbia, 65211 USA

Mr. Lee Juengermann Manager, RAM Shipping University of Missouri-Columbia 1513 Reasearch Park Drive Columbia, 65211 USA

R.H.J. (Rohen) Schuring Dangerous Goods Safety Advisor NRG Westerduinweg 3 1755 LE PETTEN P.O. Box 25 1755 ZG PETTEN, North Holland THE NETHERLANDS

Caroline Pricker Product Manager Isotopes NRG Westerduinweg 3, P.O. Box 25 1755 ZG Petten, North Holland The Netherlands Mr. Josh Burt RSO Industrial Nuclear Company, Inc. 300 HWY 146N LaPorte, 77571 USA